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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

CFN# 1939025
Facility ID# 104091

May 9, 1997

Joy Darrah, M.D.
Radiologist
Breast Clinic Wichita Kansas
8100 East 22nd Street North
Wichita, KS 67226

Dear Dr. Darrah:

Your facility was inspected on April 16, 1997 by a representative of the State of Kansas, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain parts of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

21 CFR900.12(a)(3): The medical physicist did not meet the requirement of being licensed or approved by a State, being board certified by any of the approved boards, or the alternative requirement (education, training, and experience): [REDACTED]

The specific deficiency noted above appeared under the level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

We have received your documentation submitted in response to the noncompliance found during the inspection. Based on a review of your corrective action, your facility has now met the annual MQSA inspection requirements. Please retain all documents referencing Mr. Eric Bern's meeting the initial requirements and any documentation required to meet future continuing education requirements.

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Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Deborah McGee at (214) 655-8100, extension 138. You may address any future correspondence referencing this letter to Ms. Deborah McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982.

Sincerely yours,



Edward R. Esparza
Regional Food and Drug Director

cc: Vick L. Cooper, Section Manager
Department of Health and Environment
Bureau of Air and Radiation
Forbes Field, Building 283
Topeka, KS 66620